

**ROBUST SUMMARY  
HEALTH ELEMENTS  
ACUTE TOXICITY**

**Substance Group:**           **Group 12**

**Summary prepared by:**   **Petroleum Additives Panel  
Health & Environmental Research Task Group**

# ROBUST SUMMARY HEALTH ELEMENTS ACUTE TOXICITY

<b><u>Test Substance</u></b>	
CAS #	CAS# 68855-34-5
Chemical Name	Formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur
Remarks	Test material dosed as received, purity not provided.
<b><u>Method</u></b>	
Method/Guideline followed	Similar to Test Guideline 402
Test Type	Acute dermal toxicity (Limit Test)
GLP (Y/N)	N
Year (Study Performed)	1971
Species/Strain	Rabbits/New Zealand White
Sex	Male
No. of animals/group	6
Vehicle	None
Route of administration	Dermal
Dose level	0 and 5 g/kg
Dose volume	Not provided.
Control group included	Yes
Remarks field for test conditions	<p>This study was conducted prior to the development of Test Guideline 402. This study deviated from Guideline 402 in that the skin of 3 treated animals was abraded prior to dosing. In addition the guideline calls for the evaluation of males and females using at least one dose level. This study was conducted using males only. These deviations were not considered sufficient to change the outcome of the study.</p> <p>Approximately 24 hours prior to topical application of the test material, the hair of each animal was closely clipped. On the day of dosing the skin of three treated animals was abraded prior to test material administration. A single dose of 5 g/kg of the undiluted test material was administered dermally to six male animals. The test material was kept in contact with the skin for a period of 24 consecutive hours under an elastic sheet. The application site was wiped clean of residual test material at the end of the 24-hour exposure period. The animals were observed for 14 days after treatment. The surviving animals were euthanized at the conclusion of the observation period. Gross necropsies were performed on all animals on Day 14.</p>
<b><u>Results</u></b>	LD50 > 5.0 g/kg (males)
Remarks	No signs of toxicity were observed during the 14-day observation period. Moderate skin irritation was observed when the rabbits were unwrapped after the 24-hour exposure. At necropsy, the skin appeared to be healing and no macroscopic pathological changes were

**ROBUST SUMMARY  
HEALTH ELEMENTS  
ACUTE TOXICITY**

	attributable to the test material. Pale kidneys were observed in both test and control animals.
<b><u>Conclusions</u></b>	The test article, when administered dermally as received to 6 male New Zealand white rabbits had an acute dermal LD50 of greater than 5.0 g/kg.
<b><u>Data Quality</u></b>	Reliable with restriction (Klimisch Code). Restriction due to the fact that this is a summary report.
<b><u>References</u></b>	Unpublished confidential business information
<b><u>Other</u></b>	Updated: 10/18/01

# ROBUST SUMMARY HEALTH ELEMENTS ACUTE TOXICITY

<b><u>Test Substance</u></b>	
CAS #	CAS# 68855-34-5
Chemical Name	Formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur
Remarks	Test material dosed as received, purity not provided.
<b><u>Method</u></b>	
Method/Guideline followed	FHSA 16CFR1500.3
Test Type	Acute oral toxicity
GLP (Y/N)	N
Year (Study Performed)	1971
Species/Strain	Rats/ Sprague-Dawley strain
Sex	Male
No. of animals/dose	10
Vehicle	None
Route of administration	Oral (intragastric)
Dose level	0 and 5.0 g/kg
Dose volume	Not provided
Control group included	Yes
Remarks field for test conditions	A single dose of the undiluted test material was administered intragastrically to ten fasted male rats. A control group was included. The animals were observed for signs of toxicity or behavioral changes daily. All animals were euthanized at the conclusion of the observation period. Gross autopsies were performed on all animals after 14 days.
<b><u>Results</u></b>	LD50 > 5 g/kg (males)
Remarks	No signs of toxicity were observed during the 14-day observation period. At necropsy treated and control animals exhibited pulmonary congestion and consolidation.
<b><u>Conclusions</u></b>	The test article, when administered as received to male Sprague-Dawley rats, had an acute oral LD50 > 5 g/kg.
<b><u>Data Quality</u></b>	Reliable with restriction (Klimisch Code). Restriction due to the fact that this is a summary report.
<b><u>References</u></b>	Unpublished confidential business information
<b><u>Other</u></b>	Updated: 10/18/01